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Duplex ultrasound and efficacy criteria in foam sclerotherapy from the 2nd European Consensus Meeting on Foam Sclerotherapy 2006, Tegernsee, Germany

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Summary

Rationale: The spread of foam sclerotherapy has resulted in the renaissance of sclerotherapy as a non-invasive treatment method for varicosis. An expanded European expert committee meeting in Tegernsee in April 2006 was prompted by new findings and continuous further development of the method and worked especially on the topics "The role of (duplex) ultrasound in Foam sclerotherapy" and "Evaluation of therapeutic effects of foam Sclerotherapy". It was felt that these criteria are "non-specific" to foam sclerotherapy and would possibly also be suitable for other endovenous ablative procedures. The organisers of the 2nd European Consensus Meeting on foam sclerotherapy (2nd ECMFS) were then asked to publish these recommendations in this separate publication. The entire recommendations of the 2nd ECMFS are published in an extensive overview in this journal (VASA 2008; 37; Supplement 71: 1–32).
Methodology: The 29 participants were sent a comprehensive questionnaire in advance covering all the relevant aspects of foam sclerotherapy. The organisers drew up various preliminary statements on the basis of the results. During the meeting itself the participants revised and/or approved and/or rejected these statements. For the "non-specific" topics, two working groups were given the task of conducting the concluding assessment of these items. Their final results were presented in March and April 2007.
Results: For foam sclerotherapy, duplex ultrasound is important in pre-treatment diagnosis, treatment monitoring/guidance, post-treatment efficacy evaluation and surveillance. In the pre-treatment diagnosis of varicose veins, the exact localisation of the insufficient saphenous, communicating and perforating veins is important. Duplex ultrasound is the accepted gold standard for this purpose. The application of ultrasound imaging during foam sclerotherapy increases the safety of accessing the vein in certain indications, and it can help when making a decision concerning the foam volumes to be injected, the patients' position or specific movements the patients should perform. Following treatment, the findings of duplex ultrasound, the clinical findings and the patients' symptoms can be arranged according to the recommended definitions. This allows grading of the therapeutic outcome and enables a better comparability between different treatment protocols or different treatments. Besides the evaluation of treatment success, duplex ultrasound is the method of choice to exclude or confirm complications such as deep venous thrombosis or disease progression.

Zusammenfassung

Duplex-Ultraschall- und Wirksamkeitskriterien der Schaumsklerotherapie des 2. Europäischen Konsensus-Treffens zur Schaumsklerotherapie 2006, Tegernsee, Deutschland
Hintergrund: Aufgrund neuer Erkenntnisse bei der Schaumsklerotherapie und der ständigen Weiterentwicklung der Methode fand im April 2006 ein erneutes Treffen eines erweiterten europäischen Expertengremiums statt, das besonders auch die Punkte «Die Rolle der Duplex-Sonographie bei der Schaumsklerotherapie» und «Beurteilung des Therapieerfolgs der Schaumsklerotherapie» bearbeitete. Da die beschlossenen Kriterien als «nicht spezifisch» für die Schaum-sklerotherapie erachtet werden, sondern auch bei anderen endovenösen Therapieverfahren anwendbar sind, wurden sie durch die Organisatoren des 2. Europäischen Konsensustreffens zur Schaumsklerosierung (2. ECMFS) in dieser gesonderten Publikation veröffentlicht. Die vollständigen Empfehlung des 2. ECMFS sind in einer umfassenden Gesamtpublikation in dieser Zeitschrift veröffentlicht (VASA 2008; 37; Supplement 71: 1–32.
Methodik: Auf Basis der Befragungsergebnisse bei den 29 Teilnehmern formulierten die Organisatoren eine Reihe von vorläufigen Stellungnahmen, die während des eigentlichen Treffens von den Teilnehmern überarbeitet und/oder bestätigt und/oder verworfen werden konnten. Zur weiteren Bearbeitung der beiden «nicht-spezifischen» Themengebiete wurden zwei Arbeitsgruppen eingesetzt, die eine abschließende Bearbeitung dieser Punkte durchführten und ihre Ergebnisse im März bzw. April 2007 vorstellten.
Ergebnisse: Bei der Schaumsklerosierung ist die Duplex-Sonographie zur Diagnostik vor der Therapie, zur Therapieüberwachung selbst und nach der Therapie zur Erfolgsbeurteilung und -kontrolle wichtig. Duplex-Ultraschall ist bei der Diagnostik der Varikose als Goldstandard akzeptiert. Die Anwendung der Ultraschallbildgebung während der Schaumsklerosierung erhöht die Sicherheit des Venenzugangs bei bestimmten Indikationen und kann hilfreich sein, wenn über die Menge des zu injizierenden Schaums, die Patientenposition oder bestimmte Bewegungsmanöver durch den Patienten entschieden werden muss. Nach der Therapie lassen sich die Ergebnisse der Duplex-Sonographie, die klinischen Befunde und die Symptome der Patienten gemäß der vorgeschlagenen Definitionen einordnen. Neben der Einschätzung des Therapieerfolgs ist die Duplex-Sonographie auch die Methode der Wahl um Komplikationen wie etwa eine tiefe Beinvenenthrombose auszuschließen bzw. zu bestätigen und den weiteren Verlauf der Krankheit zu beobachten.

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Introduction

The spread of foam sclerotherapy has resulted in the renaissance of sclerotherapy as a treatment method for varicosis [4]. The correct use of sclerosant foam for the right indications for various forms of varicosis has now become established world-wide as safe and effective. The joint recommendations for indications, treatment and follow-up drawn up by European experts in this field at the 1st European Consensus Meeting on Foam Sclerotherapy (1st ECMFS) in 2003 [1] were possibly able to contribute to this. The results helped to introduce a certain systematic approach to patient selection and treatment. However, while the criteria for the evaluation of the efficacy of the procedure were already addressed that time, they were not discussed in too much detail. In published literature there are no generally accepted variables to decide whether or not a treatment may be judged as "successful".

A 2nd European Consensus Meeting on Foam Sclerotherapy (2nd ECMFS) was held by an expanded European expert committee in Tegernsee, Germany, in April 2006, prompted by new findings and the continuous further development of foam sclerotherapy [2]. Experts in foam sclerotherapy were asked to contribute to this meeting if they had published or presented data, participated in clinical trials, or had otherwise scientifically or medically contributed to Foam Sclerotherapy.

It became clear during this meeting that the use of ultrasound and the evaluation of treatment efficacy have to be seen as an integral part of the procedure. Since efficacy criteria vary considerably in published data, much emphasis was put on defining the clinical and technical criteria for evaluating treatment success. Appropriate times for evaluating these were also discussed. The resulting recommendations were systematically compiled, discussed and "negotiated", and were finally considered adequate by the participants and subsequent working groups. Thus, they take into account the currently available experience, opinions and scientific knowledge of the participants at the meeting.

It was felt that these criteria are "non-specific" to foam sclerotherapy and would possibly be suitable for other endovenous ablative procedures as well. The organisers of the 2nd ECMFS were asked to publish the "non-specific" recommendations "The role of (duplex) ultrasound in foam sclerotherapy" and "Evaluation of therapeutic effects of foam sclerotherapy" in this separate publication. The entire recommendations of the 2nd European Consensus Meeting on Foam Sclerotherapy are published in an extensive overview (VASA 2008; 37; Supplement 71: 1–32).

Methodology

29 experts in the field of foam sclerotherapy were requested to comment on the recommendations of the 1st ECMFS 2003 and to urge discussion on topics that had received little if any attention to date. Evaluation of this first questionnaire led to the preparation of a second, more extensive questionnaire, dealing with a number of different topics, including personal experience, treated indications, methods of sclerosant foam preparation, sclerosant concentrations used, foam volumes injected and more. In addition, the questionnaire asked about the criteria for evaluating the efficacy of foam sclerotherapy and about the role of (duplex) ultrasound in this procedure. Beginning in March 2006, the organisers prepared approximately 100 provisional "statements" on the basis of the processed data. "Consensuses" were prepared providing that all – or almost all – of the participants had given the same or at least very similar answers to the questions. In the case of only absolute or simple majorities, responses concurring less obviously, or a low number of answers, "descriptions" of the responses were prepared.

Each statement was presented to the participants during the meeting itself in April 2006 and was discussed in depth. The participants were able to adopt, modify or even reject any of the "Consensuses" or "Descriptions". Following the discussions at the 2nd ECMFS, two working groups were given the task of conducting the concluding assessment of the items "The role of (duplex) ultrasound in foam sclerotherapy" and "Efficacy evaluation of foam sclerotherapy". Both items are closely linked, and (duplex) ultrasound has additional impact on safety aspects during and after the treatment. The working groups spent several weeks working on the final wording of the individual recommendations and presented their final results in March and April 2007 to be voted on.

Results

The Role of (duplex) ultrasound in foam sclerotherapy

Duplex ultrasound is important in pre-treatment diagnosis, treatment monitoring/guidance, post-treatment efficacy evaluation and surveillance. In the pre-treatment diagnosis of varicose veins, the exact localisation of the insufficient saphenous, communicating and perforating veins is very important. Duplex ultrasound is the accepted gold standard for this purpose [3, 6].

The ultrasound guidance of venepuncture is thought to be very important by a majority of the par-

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ticipants. It helps to confirm the intravascular placement of needles, catheter tips or any other means of vein access. Also, the injected foam can be visualised by ultrasound. It was decided by all but one expert that ultrasound guidance during the puncture and injection of *non-visible* varicose veins is *mandatory*, as specified in more detail in Consensus 1. Besides other procedures, ultrasound imaging helps to increase safety during injection. With ultrasound imaging, it can be monitored whether foam is reaching the region intended to be treated (e.g. sapheno-femoral junction). It can also be visualised whether relevant amounts of foam are reaching regions not intended to be treated (e.g. muscle veins, deep veins).

Consensus 1: Ultrasound guidance during foam sclerotherapy

For the puncture of *non-visible* varicose veins, ultrasound guidance is an important tool to prevent mispuncture. For the direct puncture and injection of non-visible great saphenous veins (GSV), small saphenous veins (SSV), perforating veins and *non-obvious* varicose veins in the groin or in the popliteal fossa, guidance by ultrasound imaging (preferably by duplex) is mandatory.
For other non-visible varicose veins, guidance by ultrasound imaging is recommended.

With ultrasound imaging, small echogenic structures (bubbles) are frequently seen in the deep venous system soon after the injection of sclerosant foam. It is believed that, after a short time, the foam bubbles turn into gas bubbles without an active sclerosant coating, i.e. without a sclerosant effect. *Routinely* performed muscle activation to flush away these bubbles is maybe not necessary if single bubbles (i.e. small amounts) are seen in the deep venous system. If large amounts are seen in the deep venous system, muscle activation has been recommended to clear the vessels of any substances with possible sclerosing properties [5].

Consensus 2: Increasing safety during GSV or SSV treatment with foam sclerotherapy

To increase safety, the following is recommended during treatment of GSV or SSV with foam sclerotherapy:
- Ultrasonographic monitoring of foam distribution
- If foam[1] is detected in the deep venous system, muscle activation such as ankle dorsiflexion should be performed
- Avoidance of immediate compression over injected areas
- Injection of very viscous foam
- No movement of the patient and leg for 2–5 minutes, no Valsalva manoeuvre and no muscle activation

[1] foam as a bolus (i.e. in an excessive amount)

Frequently, but not always, with ultrasound imaging vasospasm can be detected shortly following the injection of sclerosant foam. Published literature provides data about the frequency of vasospasm after foam injection and about the positive predictive value of vasospasm concerning *short-term* treatment success [8]. In another multicentre randomised clinical trial, the decision to re-inject sclerosant foam at the same session was based on the onset of vasospasm after the preceding injection in order to minimise the total foam volume [7]. For a slight majority of the participants, the occurrence of vasospasm of the injected vein is an indicator for the "immediate" efficacy of foam injection. On the other hand, several experts have also made the experience that a vein could re-open despite the occurrence of vasospasm (and despite "immediate" or "short-term" success). Therefore, the majority of participants felt that the occurrence of vasospasm of the injected vein was not an indicator for a (finally) sufficient foam volume or for a sufficient foam concentration. In other words, vasospasm only shows that the vein has been affected by the foam, irrespective of whether or not the volume and concentration have been sufficient to ensure a finally successful outcome.
To conclude, the use of ultrasound imaging during foam sclerotherapy increases the safety of accessing the vein in certain indications, and it *can* help when making a decision concerning the foam volumes to be injected, the patients' position or specific movements the patients should perform. A documentation of the results is, of course, possible, too.

Evaluation of the therapeutic effects of foam sclerotherapy

The easiest way of assessing the therapeutic effects of foam sclerotherapy is by clinical evaluation and according to changes in patients' symptoms. Irrespective of the modality of the clinical and technical assessment of any therapeutic effect, the optimum timeframe for this assessment should

Consensus 3: Evaluation of the therapeutic effects of foam sclerotherapy

The therapeutic effects of foam sclerotherapy in a patient's limb should be evaluated clinically and according to the patients' symptoms.
The effects of foam sclerotherapy in GSV, SSV, tributaries, recurrent varicose veins, perforating veins and venous vascular malformations should also be evaluated by duplex ultrasound.

be adhered to. Consensus was found for suitable timeframes for immediate, short-term, mid-term and long-term efficacy evaluation.
After clinical evaluation, duplex ultrasound evaluation should be performed to check treatment efficacy at least in certain indications (see Consensus 3). Duplex is the most favourable tool to evaluate the results of foam sclerotherapy in non-visible veins. The criteria are summarised in the following consensus:
The duplex findings, the clinical findings and the symptoms can be arranged according to the definitions of Consensus 7, thereby allowing the therapeutic outcome – not only of foam sclerotherapy but also of other treatment modalities – to *be graded*, enabling a better comparability between different treatment protocols or different treatments.
The question, in which patients re-injection is necessary or useful, following the grading of Consensus 7, was discussed but could not be answered during the 2nd ECMFS. There are no reliable data to answer this question at present. On the other hand, the experts made clear during the discussions that patients with a grading 2a or 2b would hardly be re-injected, and that in patients with grading 2c re-injection would sometimes be done.
The natural development of "partially successfully" treated veins (grading 1) is not clear: they could re-open completely, become occluded over the course of time, or remain "partially successful", with or without re-injection. In these patients, re-injection often depends on the clinical situation or on the symptoms, and in most of the cases most of the experts would re-inject. In published literature, it has been shown that the rate of successful treatments after ultrasound-guided foam sclerotherapy can be increased if re-injection is performed in re-opened veins after initial treatment success or in non-occluded veins after the first treatment ("secondary success") [9]. In patients with grading 0, there is a clear indication for re-treatment.
If re-treatment is done, the majority repeat the injections with the same or a lower volume of sclerosant foam of a *higher* concentration, and some participants repeat the treatment with higher volumes of foam made from a higher concentration.
Besides evaluation of the treatment success, duplex ultrasound is the method of choice to exclude or confirm complications such as deep venous thrombosis or disease progression.

Consensus 4: Evaluation of immediate and short-term therapeutic effects

Immediate effects of foam sclerotherapy on GSV, SSV, tributaries, recurrent varicose veins, perforators, reticular veins and venous vascular malformations should be evaluated after up to one week.
The short-term therapeutic effects of foam sclerotherapy on the patients' limb in general should be evaluated after 4–12 weeks and on telangiectasia 3–4 weeks after the end of treatment.

Consensus 5: Evaluation of mid-and long-term therapeutic effects

The mid-term therapeutic effects of foam sclerotherapy on the patients' limb in general, on GSV, SSV, tributaries, recurrent varicose veins, perforating veins, reticular veins, telangiectasia and venous vascular malformations, should be evaluated after 2 years, long-term results after (at least) 5 years.

Consensus 6: Duplex criteria for evaluating the effects of foam sclerotherapy

Duplex criteria for evaluating the therapeutic effects of foam sclerotherapy in the treated veins are
- Occlusion – patency
- Length of occlusion
- Flow – no flow
- Antegrade flow – reflux (> or < 1 sec)
- Compressibility of the vein
- Diameter of the vein
- Morphologic changes (fibrosis / thickening of the vein wall)
- Absence of vein

Acknowledgment

The authors appreciate that the results of the 2nd ECMFS are currently implemented into the Guidelines for Sclerotherapy 2007 of the German Society of Phlebology. The complete guidelines are/will be available at www.phlebology.de.
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1 Participant who could not attend the final Consensus Meeting but contributed through questionnaire
2 Participant who did not submit questionnaire but attended the final Consensus Meeting
3 Invited non-European participant

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Consensus 7: Definition / grading of the therapeutic effects of Foam Sclerotherapy

Grading / Name		Duplex findings	Clinical	Symptoms
2 Full success	No reflux	Complete disappearance of the treated vein or "Fibrous cord" (incompressible echogenic cord in the position of the treated vein) Complete occlusion (incompressibility) of the treated vein segment Patency of the treated vein segment with reduced diameter and antegrade flow	Normalised (i.e. no visible varices)	Absent or improved
1 Partial success	Reflux < 1 sec.	Partial incompressibility and Partial occlusion of the treated vein segment Diameter reduction	Normalised or improved (i.e. smaller Visible varices)	Absent or improved
0 No success	Reflux > 1 sec. or unchanged	Complete (or incomplete) patency and/or No change in diameter	Unchanged or worsened (i.e. larger varices and / or clinical CEAP deterioration)	Unchanged or worsened

Additional information
- Duplex evaluation is performed in an upright position
- The length of the occluded vein must be compared with the length of the insufficient part of the vein which was injected with the aim of occlusion (before injection it should be decided which part of the vein is intended to be treated). This is important for the question whether the "whole vein" is occluded after treatment
- Reflux is measured with the Valsalva manoeuvre or distal compression / decompression
- With reference to symptoms – if applicable – more differentiated and standardised symptom scores like the VSS can be used, otherwise the VAS (visual analogue scale 1–10) can be very useful and simple
- With reference to clinical findings – if applicable – more differentiated and standardised classifications such as CEAP can be used
- The definitions and gradings are applicable for all endovenous procedures (endovenous laser, radiofrequency ablation and sclerotherapy) and should allow comparison
- In the case of simultaneous treatment for medical and for aesthetic reasons, two separate questionnaires should be used
- The number of treatments (injections, sessions) and the kind of treatment used should be recorded

this very time-consuming and laborious procedure of finding all the consensuses and descriptions. Special thanks to the members of the working groups, who had to continue finding agreements even after the meeting. Lots of thanks also to Petra Düsterhöft for getting the latest relevant literature, and Hugo Partsch, Eberhard Rabe and Attilio Cavezzi for valuable advice in editing this publication. Finally, the authors acknowledge the support of Kreussler-Pharma for covering the travel expenses and accommodation of the participants and for the meeting venues.

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Addendum

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Immediate CEA for symptomatic carotid disease preferably performed under local anaesthesia is safe

asked for change of the author's list in:

M. Aleksic (1), M.A. Rueger (2), J. Sobesky (2), J. Heckenkamp (1), A.H. Jacobs (2), J. Brunkwall (1)